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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/913,960	01/02/98	MURRER	242267/MBUS1

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HM12/0128

EXAMINER
JONES, D

ART UNIT	PAPER NUMBER
1614	

DATE MAILED:

9
01/28/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/913,960

Applicant(s)
Murrer et al.

Examiner
Dwayne C. Jones

Group Art Unit
1614



☒ Responsive to communication(s) filed on 19 Nov 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-3, 5, 7, 8, and 10-13 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3, 5, and 10-13 is/are rejected.

☒ Claim(s) 7 and 8 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Status of Claims

1. Claims 1-3, 5, 7, 8 and 10-13 are pending.
2. Claims 4, 6 and 9 are canceled.
3. Claims 1-3, 5 and 10-13 are rejected.
4. Claims 7 and 8 are objected.

Response to Arguments

5. Applicants' arguments filed November 19, 1998 have been fully considered but they are not persuasive with respect to the composition claims and the method of treating hyperphosphatemia. Applicants make the following arguments. First, that the prior art reference of Junji merely discloses a large genus of salts, of which the claimed hydrates are only a single subspecies, see *In re Baird* and *In re Jones*. Second, a prima facie case has not been proven that these specific hydrates are obvious for use a pharmaceuticals. Third, the specification demonstrates that the claimed compounds have unexpected results over other hydrates of lanthanum carbonates outside the claimed range. Fourth, the instant invention is effective at absorbing phosphate at a low pH.

6. Responding to applicants' first allegation that the prior art reference of Junji merely discloses a large genus of salts, of which the claimed hydrates are only a single subspecies, see In

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re Baird and In re Jones, it is noted that Junji teaches the skilled artisan of treating hyper phosphatemia with a carbonate of a rare earth element, such as yttrium, lanthanum and cerium. This disclosure teaches the equivalence that any rare earth element is suitable to treat hyper phosphatemia as long as it is combined with a carbonate or an organic acid. Junji also teaches of the equivalence of carbonate or any organic acid. Junji further discloses of the example of cerous citrate 3.5 hydrate in treating hyper phosphatemia. The amount of 3.5 moles of the hydrate of cerous citrate is disclosed. Since Junji specifically teaches the equivalence of any rare earth element, in particular lanthanum, and a carbonate for another organic acid, the instant invention is rendered obvious. Junji's teaching that a rare earth metal with a carbonate and the specific disclosure of 3.5 moles of hydration water clearly renders the instant application obvious to one having ordinary skill in the art.

7. Applicants next argue that a prima facie case has not been proven that these specific hydrates are obvious for use a pharmaceuticals in Junji. The prior art reference of Junji is directed to treating hyper phosphatemia. For this reason, a method of treating encompasses a pharmaceutical composition claim since it would be obvious to the skilled artisan that in order to treat an ailment an active agent needs to be administered to a subject in need thereof. However, Junji does teach of an immobilizing agent for the phosphate ion which is composed of a rare earth element and a carbonate which is obviously a pharmaceutical agent.

8. Third, the specification demonstrates that the claimed compounds have unexpected results over other hydrates of lanthanum carbonates outside the claimed range. The data in Table 1

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shows that Sample 6, which has 3.8 waters of hydration, has removed 88.1% of the phosphate from solution. The compound of Junji teaches of an equivalent corresponding rare earth metal salt which has 3.5 waters of hydration. Since the 3.5 waters of hydration falls within the instantly claimed range, the compounds of Junji would also possess similar properties, particularly with respect to the removal of phosphate from a subject in need thereof.

9. Fourth, the instant invention is effective at absorbing phosphate at a low pH. The prior art reference of Junji clearly teaches of providing an immobilizing agent for the phosphate ion which is effective for treating hyper phosphatemia. Junji also discloses that the immobilizing agent, composed of rare earth metal salt, selectively and irreversibly reacts with the phosphate ion in high efficiency. Since Junji teaches that the immobilizing agents of the phosphate ion are highly efficient and effective, one having ordinary skill in the art would be motivated to use the immobilizing agents of Junji to a subject in need of lowering the phosphate ion level in varying pH levels not just those of the digestive tract. Even still, the digestive tract does encompass the stomach and the GI tract.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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11. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 has dependency on canceled claim 4. This makes claim 5 vague and indefinite.

Claim Objections

12. Claims 7 and 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 103

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

14. The rejection of claims 1-3, 5 and 10-13 under 35 U.S.C. 103(a) as being unpatentable over Junji of JP 62145024 for both the above-stated and reasons of record.

Conclusion

15. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

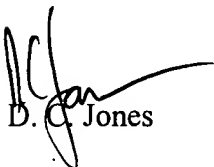
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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

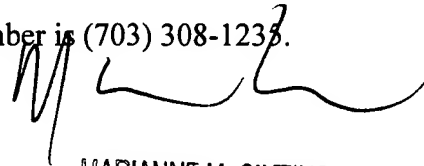
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1233.



D. C. Jones

January 21, 1999



MARIANNE M. CINTINS
SUPERVISORY PATENT EXAMINER
GROUP 120